



## PCT

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference L/AH66/VA/15		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/EP 02/04207		International filing date (day/month/year) 12.04.2002	Priority date (day/month/year)	
International Patent Classification (IPC) or national classification and IPC A61K9/16				
Applicant CAMPINA NEDERLAND HOLDING B.V.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 22.09.2003		Date of completion of this report 01.09.2004		
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Uhl, M Telephone No. +49 89 2399-8654 		

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP 02/04207

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-9 as originally filed

**Claims, Numbers**

1-26 received on 17.06.2004 with letter of 17.06.2004

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-26
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-26
Industrial applicability (IA)	Yes: Claims	1-26
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/EP 02/04207

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following document/s/:

D1: EP-750492

Claim 1 of the present application is now omitting the antrone reaction which was seen as unusual if used in connection with a twin stage impinger. All claims are now clear and the international search report is regarded to cover all the now claimed subject matter.

The document D1 is regarded as remaining the pertinent prior art for the subject-matter of the present invention and discloses primary particles from 1-15 $\mu$ m with particles (=pellets) made thereof in dimensions of 50-1000 $\mu$ m (preferred 150-1000 $\mu$ m, most preferred 200-800 $\mu$ m). These pellets are said to be stable enough to be packaged, transported or stored but will be disrupted into independent primary particles upon egress into the turbulent airstream within the inhaler. The excipient used is lactose and the medicaments transported with such pharmaceutical form are those usually formulated in inhalation therapy (see §9 of D1). The wet preparation is disclosed in col.4, l.16-31 of D1 with an implicit final drying step before contacting the pellets with medicament (see §16, where it is mentioned that the pellets should be stored under unhydrous conditions which is equivalent to drying; it should be kept in such a way that free water is less than 1%). As D1 covers the whole technology necessary to produce said pellets from primary particles, even a choice of another excipient than lactose seems not to be inventive over this prior art as being considered as an arbitrary choice out of the list of normal substances at hand for the skilled person without exerting an inventive activity. The only difference to this prior art product is the characterisation by specifying the amount of excipient which reaches the stage 2 of a twin stage impinger. Such characterisation renders subject matter of claims 1-26 novel over the cited prior art. However the procedural steps which shall lead to the product which falls under the definition of the parameter seem to be identical to those in D1 which leads to the following objection : subject matter of claims 1-26 seems not to be inventive in view of D1 = EP750492 (citations see international search report) as the definition by a parameter reached in the twin stage impinger is seen as an arbitrary choice without exerting an inventive activity. The different ways of drying the granules or the nature of the basic substance like lactose is also seen as a choice within different possibilities at hand for the skilled person without exerting an inventive activity.